J. Pharm Pract Comm Med, 2026; 12(2):102-104.
www.jppcm.org

Original Article

Adverse Drug Reaction Reporting in Bangladesh: Current Scenario, Barriers, and Strategies for Improvement

Faruque Alom*, Mehedi Hasan

Department of Pharmacy, Gono Bishwabidaylay, Dhaka, BANGLADESH.

ABSTRACT

Background: Adverse Drug Reactions (ADRs) are a major cause of morbidity, mortality, and increased healthcare costs worldwide. Pharmacovigilance systems play a crucial role in ensuring medication safety; however, ADR reporting remains inadequate in many developing countries, including Bangladesh. **Objectives:** This study aimed to assess physicians' knowledge, awareness, attitudes, and practices regarding ADR reporting in Bangladesh and to identify barriers and possible strategies to improve spontaneous reporting. **Materials and Methods:** A cross-sectional observational study was conducted between December 2018 and March 2019 among 50 physicians working in different hospitals. Data were collected using a predesigned structured questionnaire assessing knowledge, awareness, practices, attitudes, and perceived barriers related to ADR reporting. Data were analyzed descriptively and expressed as percentages. **Results:** Although most physicians perceived ADR reporting as a necessary and professional obligation, only a small proportion had ever reported an ADR. Major barriers included a lack of knowledge regarding reporting procedures, unavailability of reporting forms, lack of time, and insufficient clinical confidence. Most physicians supported compulsory ADR reporting. **Conclusion:** Despite positive attitudes toward ADR reporting, awareness, and actual reporting practices among physicians in Bangladesh remain inadequate. Strengthening training programs, simplifying reporting systems, and increasing institutional and governmental support are urgently needed to enhance pharmacovigilance and patient safety.

Keywords: ADR Reporting, Adverse Drug Reaction, Bangladesh, Pharmacovigilance, Physicians.

Correspondence:
Faruque Alom
Department of Pharmacy, Gono Bishwabidaylay, Dhaka, BANGLADESH.
Email: alomfaruque765@gmail.com

INTRODUCTION

Pharmacovigilance is an essential component of healthcare systems aimed at ensuring patient safety through the detection, assessment, understanding, and prevention of Adverse Drug Reactions (ADRs). With the continuous introduction of new medicines and increasing drug utilization, monitoring drug safety has become increasingly important worldwide (Bangladesh National Formulary, 2015).

In Bangladesh, the Directorate General of Drug Administration (DGDA) serves as the national regulatory authority responsible for pharmacovigilance activities in collaboration with the World Health Organization-Uppsala Monitoring Centre (Bateman *et al.*, 1992). An ADR Monitoring Cell was established within DGDA in 1996 to facilitate spontaneous reporting by healthcare professionals (Directorate General of Drug Administration, 2017). Despite these initiatives, ADR reporting in Bangladesh remains limited.

Previous studies suggest that the incidence of ADRs in Bangladesh is comparable to that in other countries; however, under-reporting remains a major concern (Edwards and Aronson, 2000; Hazell and Shakir, 2006; Mustansir *et al.*, 2013). Inadequate awareness, lack of training, time constraints, and weak reporting mechanisms contribute significantly to poor reporting practices. Understanding physicians' knowledge, attitudes, and practices regarding ADR reporting is therefore crucial for strengthening the national pharmacovigilance system.

OBJECTIVES

1. To identify factors influencing voluntary reporting of adverse drug reactions among physicians.
2. To assess physicians' knowledge, awareness, and attitudes toward ADR reporting in Bangladesh.

MATERIALS AND METHODS

A cross-sectional observational study was conducted between December 2018 and March 2019 among physicians working in different hospitals. A total of 50 physicians participated in

OPEN ACCESS

Manuscript TECHNOMEDIA

DOI: 10.5530/jppcm.20260375

Publishing Partner : Manuscript Technomedia. [www.mstechnomedia.com]

the study, including professors, associate professors, assistant professors, registrars, junior consultants, resident physicians, and medical officers.

Data were collected using a predesigned structured questionnaire developed to assess demographic characteristics, knowledge of ADR reporting, awareness and practices related to ADR reporting systems, attitudes toward ADR reporting, perceived barriers, and suggestions for improving reporting practices.

The questionnaire was distributed during workshops and seminars held in teaching hospitals. The purpose of the study was explained to the participants, and completed questionnaires were collected immediately to ensure a high response rate. Data were entered into a computer database and analyzed descriptively. Results were expressed as frequencies and percentages.

RESULTS

All participating physicians were from nongovernment institutions. The majority were male, and most respondents were medical officers and medicine specialists.

Regarding knowledge of ADR reporting, most physicians perceived that doctors are primarily responsible for reporting ADRs. Allopathic medicines and vaccines were considered the most important agents requiring reporting. Serious reactions and patient deaths due to ADRs were perceived as priority events for reporting.

Awareness and practice of ADR reporting were found to be inadequate. Less than half of the physicians were aware of the national ADR reporting and monitoring system in Bangladesh, and only a small proportion had ever reported an ADR to any reporting or monitoring center. Awareness of hospital-based ADR reporting systems was also limited, and very few physicians had reported ADRs at the institutional level.

Attitudinal assessment revealed that the vast majority of physicians believed ADR reporting is necessary and a professional obligation. Most respondents supported compulsory ADR reporting rather than voluntary reporting.

Several barriers to ADR reporting were identified. The most commonly reported barriers included lack of knowledge regarding where, how, and when to report ADRs, unavailability of reporting forms, lack of time to complete reporting, insufficient clinical knowledge to identify ADRs, and concern that reporting may generate additional workload.

Physicians suggested several strategies to improve ADR reporting, including strengthening training programs, making ADR reporting compulsory during in-service training, increasing institutional involvement, simplifying reporting systems, ensuring availability of reporting forms, and incorporating ADR reporting into undergraduate medical education.

DISCUSSION

The present study demonstrates that pharmacovigilance and ADR reporting practices in Bangladesh remain at an early stage. Despite generally positive attitudes toward ADR reporting, actual reporting practices among physicians are poor. Similar findings have been reported in other developing countries, where under-reporting is commonly attributed to lack of awareness, time constraints, and inadequate institutional support (Mustansir *et al*., 2013; WHO-UMC, 2018; World Health Organization, 2002).

Educational interventions targeting healthcare professionals may significantly improve knowledge and confidence in identifying and reporting ADRs. Simplifying reporting mechanisms and providing regular feedback from regulatory authorities may further encourage spontaneous reporting. Expanding awareness that ADR reporting can involve other healthcare professionals, such as nurses and dentists, may also contribute to improved reporting rates.

The study concludes that while physicians in Bangladesh generally maintain a positive and professional attitude toward Adverse Drug Reaction (ADR) reporting, there is a significant disconnect between their beliefs and their actual clinical practices. Despite the establishment of a national ADR Monitoring Cell within the Directorate General of Drug Administration (DGDA) as early as 1996, the pharmacovigilance system in Bangladesh remains in its nascent stages, characterized by chronic under-reporting that mirrors challenges seen in other developing nations. The research highlights a critical gap: although most respondents recognize ADR reporting as a professional obligation and perceive it as necessary for patient safety, only a small fraction have ever submitted a report to a monitoring center.

Several systemic and individual barriers contribute to this inadequacy. Key obstacles identified include a fundamental lack of knowledge regarding the specific procedures of "where, how, and when" to report, as well as a lack of clinical confidence in identifying reactions. These are compounded by logistical hurdles, such as the unavailability of reporting forms, perceived time constraints during busy clinical shifts, and concerns regarding the additional workload that reporting might generate. Interestingly, the study found that most physicians favor a transition from the current voluntary system to a compulsory ADR reporting framework, suggesting a willingness to comply if the system is more structured.

To address these deficiencies and move toward a more robust safety culture, the study calls for urgent, multi-faceted interventions. Strengthening training programs and incorporating pharmacovigilance into both undergraduate medical education and in-service training are essential to building the necessary technical competence among healthcare providers. Furthermore, simplifying the reporting mechanisms, ensuring the consistent

availability of forms at the institutional level, and increasing governmental and institutional support are vital steps. Ultimately, fostering an environment where reporting is streamlined and encouraged will play a pivotal role in enhancing patient safety and ensuring the rational use of medicines across the healthcare landscape of Bangladesh.

CONCLUSION

This study highlights that although physicians in Bangladesh generally hold a positive attitude toward adverse drug reaction (ADR) reporting, their actual reporting practices remain limited. Key barriers such as inadequate knowledge of reporting procedures, lack of accessible reporting systems, and time constraints continue to hinder effective pharmacovigilance. Addressing these challenges through targeted training, simplified reporting mechanisms, and stronger institutional and regulatory support is essential. Improving ADR reporting practices will play a crucial role in enhancing patient safety and promoting the rational use of medicines in Bangladesh.

LIMITATIONS

The small sample size and limited institutional coverage restrict the generalizability of the findings. In addition, the questionnaire-based design may be subject to reporting bias. Future studies using qualitative methods and larger, nationally representative samples are recommended.

This study indicates that awareness and practice of ADR reporting among physicians in Bangladesh remain inadequate despite positive attitudes toward pharmacovigilance. There is an urgent need to strengthen ADR reporting through targeted training programs, simplified reporting mechanisms, institutional support, and strong governmental policies. Improved ADR reporting will play a vital role in enhancing patient safety and promoting rational use of medicines in Bangladesh.

ACKNOWLEDGEMENT

The authors would like to thank all physicians who voluntarily participated in this study.

ABBREVIATIONS

ADR: Adverse drug reaction; **DGDA:** Directorate General of Drug Administration; **WHO:** World Health Organization; **WHO-UMC:** World Health Organization-Uppsala Monitoring Centre; **KAP:** Knowledge, Attitudes, and Practices.

FUNDING

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHOR CONTRIBUTIONS

Faruque Alom contributed to study conception and design, data collection, data analysis, manuscript preparation, and final approval. Mehedi Hasan contributed to data interpretation, manuscript review, and final approval.

ETHICAL APPROVAL AND CONSENT TO PARTICIPATE

This study was conducted in accordance with ethical principles for research involving human participants. Participation was voluntary, and informed consent was obtained from all participants before data collection. No personal identifiers were collected, and confidentiality of the participants was strictly maintained.

REFERENCES

Bangladesh National Formulary (2015). In *Bangladesh national formulary* (5th ed). Dhaka: DGDA.

Bateman, D. N., Sanders, G. L., and Rawlins, M. D. (1992). Attitudes to adverse drug reaction reporting in hospital doctors. *British Journal of Clinical Pharmacology*, *34*(5), 421-426. PubMed: 1467137.

Directorate general of drug administration. *Pharmacovigilance activities in Bangladesh*. Dhaka: DGDA. Ministry of Health and Family Welfare (2017).

Edwards, I. R., and Aronson, J. K. (2000). Adverse drug reactions: Definitions, diagnosis, and management. *Lancet*, *356*(9237), 1255-1259. doi: 10.1016/S0140-6736(00)02799-9, PubMed: 11072960.

Hazell, L., and Shakir, S. A. (2006). Under-reporting of adverse drug reactions: A systematic review. *Drug Safety*, *29*(5), 385-396. doi: 10.2165/00002018-200629050-00003, PubMed: 16689555.

Mustansir, T., Rahman, M. M., and Islam, M. A. (2013). Pharmacovigilance practices and adverse drug reaction reporting in Bangladesh. *Bangladesh Journal of Pharmacology*, *8*(4), 456-462.

WHO-UMC (2018). Uppsala: World Health Organization Collaborating Centre for International Drug Monitoring. *The* WHO *Programme for International Drug Monitoring*.

World Health Organization (2002). *The importance of pharmacovigilance: Safety monitoring of medicinal products*. Geneva: WHO.

Cite this article: Alom F, Hasan M. Adverse Drug Reaction Reporting in Bangladesh: Current Scenario, Barriers, and Strategies for Improvement. J Pharm Pract Comm Med. 2026;12(2):102-4.